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S. 2195

To provide for the regulation of human tissue for transplantation to ensure that such tissue is handled in a manner to preserve its safety and purity, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 3, 1996

Mr. WYDEN (for himself, Mr. DODD, and Mr. SIMON) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To provide for the regulation of human tissue for transplantation to ensure that such tissue is handled in a manner to preserve its safety and purity, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. HUMAN TISSUE.

(a) IN GENERAL.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(hh)(1) The term 'human tissue' means a collection of similar human cells which—

''(A) is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or condition in a human or for reproduction;

''(B) achieves its primary intended purpose through repair or replacement of bodily tissue by structural support or cellular function;

''(C) may have been propagated or otherwise processed before use;

''(D) may be combined with substances that are safe under conditions of intended use and not intended to provide a therapeutic effect; and

''(E) includes reproductive tissue, demineralized bone, heart valves, dura mater, and manipulated autologous cells.

''(2) The term 'human tissue' does not include vascularized human organs, gene therapy, blood, soluble blood components, milk, or products made by combining human tissue with biomaterials.

''(3) Human tissue is not a drug, biological product, or device unless reclassified by the Secretary pursuant to section 352A of the Public Health Service Act.''.

(b) REGULATION OF HUMAN TISSUE.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following section:

''REGULATION OF HUMAN TISSUE

''SEC. 352A. (a) SUBJECT TO REGULATION.—

''(1) IN GENERAL.—Human tissue shall be subject to regulation under this section only if the Secretary publishes a finding in the Federal Register, after a hearing before the Commissioner, that voluntary regulation under generally accepted scientific standards is inadequate to protect the public health with respect to any particular type of human tissue or human tissue generally.

''(2) EXCEPTION.—Human tissue shall not be subject to regulation as a drug, biological product, or device unless it is reclassified under subsection (f).

''(b) REGISTRATION.—

''(1) IN GENERAL.—Any person subject to regulation under this section who recovers, processes, stores, or distributes human tissue for transplantation or implantation in the United States shall register in accordance with the registration procedures established for drugs under section 510 of the Federal Food, Drug, and Cosmetic Act. Such registration shall contain the name of the person, the location of its facilities, a list of the types of human tissue recovered, processed, stored, or distributed by

such person, and a brief description of the basic method or methods of processing of such tissue.

''(2) AUTHORIZED ACTIVITIES.—A person registered in accordance with paragraph (1) shall be deemed to be authorized to conduct human tissue recovery, processing, storage, and distribution activities as identified in the applicable registration unless—

''(A)(i) the Secretary determines, upon inspection, that such person fails to meet applicable operating standards under subsection (c);

''(ii) the Secretary notifies such person of a determination under clause (i), advises the person of the steps necessary to meet such standards, and provides the person with a reasonable opportunity to establish compliance with the standards;

''(iii) the Secretary determines, after an opportunity for an informal hearing, that the person has failed to establish compliance as provided for in clause (ii) within the applicable period and such failure constitutes a threat to the public health; and

''(iv) the Secretary suspends or revokes the authority to conduct such activities;

''(B) the Secretary determines, after an opportunity for an informal hearing, that such person has failed to comply with any patient registry or other retrospective patient data requirement, and the Secretary suspends or revokes the authority to conduct such activities; or

''(C) the Secretary determines that such person presents an immediate or substantial danger to the public health, and the Secretary suspends or revokes the authority to conduct such activities, in which case an informal hearing shall be conducted within 5 business days of the date of such suspension or revocation.

''(c) OPERATING STANDARDS.—The Secretary may establish, after notice and opportunity for comment, operating standards for human tissue that shall be limited to the following general requirements for the recovery, processing, storage, and shipment of human tissue:

''(1) Requirements for infection control designed to prevent transmission of disease.

''(2) Requirements for processing practices that assure the safety of, and prevent damage to, human tissue.

''(3) Requirements for labeling and record-keeping to identify the type of tissue and any added foreign substance and to permit tracing.

''(d) LABELING AND ADVERTISING.—Statements made in labeling, advertising or promotional materials regarding clinical benefit with respect to human tissue shall consist only of accurate and balanced representations that are consistent with sound scientific information, including current data from a registry required or established under subsection (e), if available.

''(e) REGISTRY.—A person registered under subsection (b) may be required by the Secretary to maintain a patient registry or meet other retrospective patient data requirements if, after notice and an opportunity for comment, the Secretary determines that such tissue has been commercially available within the United States for a period of less than 5 years and that such data requirement is necessary to protect the public health.

''(f) RECLASSIFICATIONS.—

''(1) HUMAN TISSUE.—The Secretary may reclassify a particular type of human tissue as a drug, biological product or device if, after notice and an opportunity for comment, the Secretary determines that—

''(A) with respect to the particular type of human tissue—

''(i) the tissue is subject to a patient registry or other retrospective data requirement under which the collection of information has been required for at least 5 years (or such other time period as agreed to by the Secretary and the registered person); and

''(ii) the information received from such patient registry or other retrospective data requirement is insufficient to confirm the safety and clinical benefit from the use of such tissue; or

''(B) a particular type of human tissue should be reclassified because it presents an imminent hazard to public health.

''(2) UPON SECRETARIAL ACTION.—The Secretary may reclassify a human drug, biological product or medical device as human tissue if the Secretary determines, after notice and an opportunity for comment, that such previous classification is not necessary to protect public health.

''(3) UPON PETITION.—The Secretary may reclassify a drug, biological product, medical device, or

human tissue upon the petition of the sponsor of such drug, biological product or device, or the registered person for such human tissue, if, after notice and an opportunity to comment, the Secretary finds that such reclassification is consistent with the protection of public health.

''(g) ENFORCEMENT.—

''(1) IN GENERAL.—If the Secretary determines that any person has violated any provision of this section or any regulations promulgated under this section, and the Secretary determines that the violation constitutes a significant risk to the public health, the Secretary may issue an order that such person cease distribution of human tissue, or that human tissue recovered, processed, stored or distributed by such person be retained, recalled, or destroyed. After receipt of such an order, the person in possession of the human tissue shall not distribute or dispose of the human tissue in any manner inconsistent with the provisions of the order.

''(2) HEARING.—A person subject to the order under paragraph (1) may obtain an informal hearing regarding the order if the person requests such a hearing not later than 5 days after receiving the order. If the person does make such a request within

such period, the Secretary shall conduct the hearing within 30 days after receiving the request and shall issue an order not later than 15 days after the hearing is conducted. Such order shall be considered a final order of the Secretary.

''(h) INSPECTION.—Each person registered under subsection (b) shall be subject to inspection under section 704 of the Federal Food, Drug, and Cosmetic Act. The Secretary may, with the concurrence of the registered person, authorize an inspection to be conducted by any person specifically accredited by the Secretary to conduct such inspection under section 712 of such Act.

''(i) CORD BLOOD.—

''(1) IN GENERAL.—This section (including provisions regarding reclassification) shall apply with respect to cord blood to the same extent and in the same manner as this section applies with respect to human tissue.

''(2) IMPLEMENTATION.—The Secretary shall implement this section with respect to cord blood under regulations promulgated after notice and opportunity to comment.

''(j) EYES.—The Secretary shall not regulate eyes until such time as the Secretary makes a finding under this section that voluntary regulation under generally ac-

cepted standards is inadequate to protect the public health.''.

(c) TRANSITION.—The requirements of the interim regulation, promulgated by the Secretary of Health and Human Services on December 11, 1993, shall remain in effect until amended or withdrawn by the Secretary. Any modifications to such regulations after the date of the enactment of this Act are subject to this Act and the amendments made by this Act.

(d) EFFECTIVE DATE.—The amendment made by subsection (c) shall take effect on June 30, 1997.

(e) CONFORMING AMENDMENTS.—

(1) ADULTERATION PROVISION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended—

(A) in the first sentence by striking ''drug or device'' and inserting ''drug, device or human tissue''; and

(B) by adding at the end thereof the following:

''(j) if it is human tissue and it is recovered, processed, stored, or distributed by—

''(1) a registered person under section 352A of the Public Health Service Act whose failure to com-

ply with standards constitutes a threat to public health; or

''(2) a person who is required under such section to register but has failed to do so.''.

(2) MISBRANDING PROVISIONS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended:

(A) in the section heading, but striking ''MISBRANDED DRUGS AND DEVICES'' and inserting the following: ''MISBRANDED DRUGS, DEVICES, AND HUMAN TISSUE''; and

(B) in the first sentence, by striking ''drug or device'' and inserting ''drug, device or human tissue''.

(3) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end thereof the following:

''(v) The adulteration or misbranding of any human tissue.''.

(4) SEIZURE.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(A) in subsection (a)(2)(D), by inserting ''or human tissue'' after ''device''; and

(B) in the first sentence of subsection (d)(1), by striking ''or cosmetic'' and inserting ''cosmetic, or human tissue''.

(5) INSPECTION.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended—

(A) in the first sentence, by inserting ''human tissue,'' after ''device,'' each place such appears; and

(B) in the second sentence, by inserting ''human tissue,'' after ''drugs,'' each place such appears.

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